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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/147,770  | 04/28/1999  | PIERO DEL SOLDATO    | P8907-9002          | 2174             |
| 7590  | 06/06/2005  |                      | EXAMINER            |                  |
| AREN'T FOR KINTNER PLOTKIN & KAHN<br>1050 Connecticut Avenue N W Suite 600<br>Washington, DC 20036-5339 |             |                      | MITCHELL, GREGORY W |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1617                |                  |

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/147,770             | DEL SOLDATO ET AL.  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Gregory W. Mitchell    | 1617                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 16 March 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,2,9,10 and 26 is/are pending in the application.  
 4a) Of the above claim(s) 26 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2,9 and 10 is/are rejected.  
 7) Claim(s) 1 and 2 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

This Office Action is in response to the Election filed March 16, 2005. Claims 1, 2, 9, 10 and 26 are pending. Claim 26 is withdrawn from consideration as being drawn to a non-elected invention. Claims 1, 2, 9 and 10 are examined herein.

The 35 USC 103 rejection of claims 1 and 2 over Scherrer et al. and Matji et al., in view of Persson et al. and Chung et al. in the Office Action dated December 03, 2003 is hereby withdrawn. The following rejections now apply.

### *Election/Restrictions*

Applicant's election with traverse of Group VII in the reply filed on March 16, 2005 is acknowledged. The traversal is on the ground(s) that (1) there is no lack of unity because there was no lack of unity found in the PCT application; (2) there is no lack of unity because the inventive concept relates to the NO<sub>2</sub> group attached to the various compounds; (3) there is no lack of unity because the compounds have common chemical structures and similar pharmacological activities; (4) there is no lack of unity because the compounds are useful for the same purpose, namely the treatment of urinary incontinence; (5) the compounds of the present application have improved activity against urinary incontinence when compared to their corresponding parent drug; and (6) there was a showing of unexpected results for compounds of claims 9 and 26.

This is not found persuasive because US examination practice is different from that of PCT practice and Examiner has shown in the Restriction Requirement mailed February 24, 2005 that the compounds do not share a common core and, therefore,

lack unity. It is also noted that the parent PCT application of the instant case was not examined in the US. The USPTO is not bound by the findings of another patent office. It is further pointed out that unity of invention was found to be lacking in the PCT application. Furthermore, claims 1-6 of the PCT application were searched only *partially*. The international search report states "In view of the great number of compounds for which protection is being sought in claim 1, the search as been restricted for economical reasons to compounds of the examples and the first inventive concept". Applicant's arguments regarding the showing of unexpected results and similarity of pharmacological utility is not persuasive because, for the reasons of record, the compounds do not share a common core and, therefore, do not possess a special technical feature or unity of invention.

The requirement is still deemed proper and is therefore made **FINAL**.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 02, 2004 has been entered.

***Claim Objections***

Claims 1 and 2 are objected to for being drawn, in part, to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because R is undefined wherein t is 0.

Claim 2 is rejected for depending from an indefinite claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Del Soldato et al. (WO 95/30641).

Del Soldato et al. discloses the genus of compounds as anti-inflammatory agents within which the currently claimed compound is a species (pp. 1, 6, 23, 28-29, claim 1). Del Soldato et al. does not specifically disclose the claimed species.

Absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the specific compound as instantly claimed because it falls within the scope of the genus disclosed by Del Soldato et al. One would have been motivated to prepare the species claimed because of an expectation of success in prepare an agent suitable for anti-inflammatory treatments, as taught by Del Soldato et al.

Claims 1, 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Del Soldato et al. as applied to claim 9 above, and further in view of Armour et al. (USPN 5703240).

Del Soldato et al. applies as disclosed above. Del Soldato et al. does not specifically teach the treatment of urinary incontinence.

Armour et al. teaches that urinary incontinence is an inflammatory disorder and teaches the use of anti-inflammatory agents for the treatment of urinary incontinence (col. 6, lines 53-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat urinary incontinence with the compounds of Del Soldato et al. because (1) Del Soldato et al. teaches the compounds disclosed therein as anti-inflammatory agents; (2) Armour et al. teaches that urinary incontinence is an inflammatory disorder;

and (3) Armour et al. teaches the use of anti-inflammatory agents for the treatment of urinary incontinence. Since the Del Soldato et al. and Amour et al. references both teach anti-inflammatory agents, the skilled artisan would have been motivated by an expectation of success to substitute the agents in a treatment of urinary incontinence.

***Response to Arguments/Amendments***

Applicant's arguments filed April 02, 2004 with respect to claims 1-2 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Del Soldato et al. (WO 95/09831).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm



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SUPERVISORY PATENT EXAMINER